K122115

NOV 1 2012

510(k) SUMMARY

1. Applicant Information

Applicant Name:	Collagen Matrix, Inc.
Address:	15 Thornton Road Oakland, New Jersey 07436
Telephone:	(201) 405-1477
Fax:	(201) 405-1355
Contact Person:	Peggy Hansen, RAC VP, Clinical, Regulatory, QA, and Marketing
Date Prepared:	October 4, 2012

2. Name of the Device

Device Common Name:	Collagen Wound Dressing
Device Trade Name:	Collagen Dental Wound Dressings
Device Classification Name:	Dressing, Wound, Collagen KGN Unclassified

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collacare Dental, Collagen Dental Matrix K110388 Collagen Wound Dressing - Oral K040403

4. Description of the Device

Collagen Dental Wound Dressings are absorbent, porous, collagen matrices engineered from highly purified type I collagen derived from porcine Achilles tendon. The Collagen Dental Wound Dressings are applied directly to the wound and protect the wound and delicate new tissue. Collagen Dental Wound Dressings are supplied sterile, non-pyrogenic, in various sizes, and for single use only.

5. Intended Use

Collagen Dental Wound Dressings are intended for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites

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- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

6. Summary/Comparison of Technical Characteristics

Collagen Dental Wound Dressings and their predicates have similar technological characteristics. In particular, the Collagen Dental Wound Dressings and the predicates are similar with respect to intended use, purified starting material (type I collagen), form, sizes, physical integrity. The substantial equivalence of Collagen Dental Wound Dressings and their predicates was demonstrated based on in vitro characterization studies, biocompatibility studies, and clinical history of the predicate devices.

In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

Collagen Dental Wound Dressing representative products have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The products passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices. No clinical tests were performed on the product, however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies as well as *in vitro* and *in vivo* biocompatibility studies show that Collagen Dental Wound Dressings are safe and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 1 2012

Collagen Matrix, Incorporated
Ms. Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance, & Marketing
15 Thornton Road
Oakland, New Jersey 07436

Re: K122115
Trade/Device Name: Collagen Dental Wound Dressings
Regulation Number: Unclassified
Regulation Name: Dressing, Wound, Collagen
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 4, 2012
Received: October 5, 2012

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Dental Wound Dressings

Indications for Use:

Collagen Dental Wound Dressings are intended for the management of oral wounds and sores, including:

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- Burns
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- Surgical wounds
- Traumatic wounds

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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